

CD HORIZON® Spinal System
510(k) Summary
January 22, 2013

FEB 22 2013

I. Company: Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: Sowmya Shetty
Regulatory Affairs Specialist

II. Proprietary Trade Name: CD HORIZON® Spinal System

III. Classification Name: Spinal Interlaminar Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, and Pedicle Screw Spinal System (21 CFR 888.3050, 888.3060 and 888.3070)

IV. Classification: Class III (Pre-amendment)

V. Product Codes: KWP, KWQ, MNH, MNI, NKB and OSH

VI. Product Description

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

A subset of CD HORIZON® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws, CROSSLINK® Plates, and connecting components. Similarly to the CD HORIZON® implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The system also includes various instruments used to assist in the implantation of the system via minimally invasive approaches.

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The purpose of this 510(k) is to inform the Agency of changes to the SEXTANT® instruments cleared in K051674 (SE 07/21/05), and K063147 (SE 01/18/07) since the time of their original clearance.

VII. Indications

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis; trauma; and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

VIII. Summary of the Technological Characteristics

The subject CD HORIZON® SEXTANT® instruments assist in the percutaneous implantation of the CD HORIZON® Spinal System in a manner identical to the predicate SEXTANT® instruments. The subject instruments have the same single and multi-level assemblies, same material (stainless steel), function and surgical technique (method of use) as the predicate instruments. The subject instruments are similar in design except for minor modifications which do not affect the form, fit or function of the instruments. The subject instruments still maintain the same intended use and indications as the predicate devices.

IX. Identification of Legally Marketed Devices

The design features, materials and indications for use of the subject devices are substantially equivalent to the predicate CD HORIZON® SEXTANT® instruments cleared in K051674 (SE 07/21/05), K063417 (SE 01/18/07) and K102807 (SE 11/17/10). The device labeling and instrument reprocessing labeling are identical to that cleared in K122862 (SE 10/03/12).

X. Discussion of the Non-Clinical Testing

Non-clinical testing in the form of design validation and verification activities (validation lab and tolerance stacks) was performed. These activities demonstrated that the subject SEXTANT® instruments function as intended and raise no new issues of safety and effectiveness as compared to the predicate devices.

XI. Conclusions

A risk analysis was completed for the changes made to the subject devices. Based on the non-clinical testing and additional supporting documentation provided in this pre-market notification, Medtronic believes the subject devices demonstrated substantial equivalence to the previously listed predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Medtronic Sofamor Danek USA, Incorporated
% Ms. Sowmya Shetty
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K123809

Trade/Device Name: CD HORIZON® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: January 22, 2013
Received: January 25, 2013

Dear Ms. Shetty:

This letter corrects our substantially equivalent letter of February 22, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

ErinFDKeith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123809

Device Name: CD HORIZON® Spinal System

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

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(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K123809